Implementing Ethics Policies in Developing Countries: Ploughing On Parched Ground?

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Authors' Note

The ideas for this paper originated from experiences gathered during the implementation of the Ethics Policy at the University of Botswana beginning in May 2005, and the deliberations of an international ethics conference held in Durban, South Africa in October 2006. The ideas were further developed from discussions during the Southern African Research Innovation and Management Association (SARIMA) conference held in Pretoria, South Africa, in May 2006.

Abstract

It is globally expected that universities will ensure that policies guiding researchers' conduct are in place and adhered to. This expectation is not waived in developing countries. Successful implementation of an ethics policy is facilitated by an appropriate national regulatory framework on which to base the argument for compliance. However, it is possible to implement such policies even when a regulatory framework is absent. The University of Botswana implemented a program to increase awareness of research ethics and to manage allegations of research misconduct through a needs assessment and seminars on the Responsible Conduct of Research (RCR). This paper describes this problem, and the success of the program initiated to address it. This program serves as a model for other research institutions in the developing world that may encounter similar challenges.

Introduction

Research integrity is a global concern. When research lacks integrity, it destroys public trust in the academic and scientific community (The National Academies Press, 2002). While this issue is important for all research institutions, it becomes increasingly complex in the setting of internationally collaborative research, in which local standards vary despite considerable global consensus regarding many aspects of research integrity and ethics.

International interest in research ethics became pronounced following World War II (Deyhle, Hess & LeCompte, 1992). This interest resulted from the inhumane treatment of human beings by Nazi physicians (Crigger, 1992). Subsequently, numerous bodies offered standards to help ensure the ethical conduct of research (CIOMS; Declaration of Helsinki). While there are some differences among these policies, most support the prospective review of research and informed consent.

In addition, every profession is governed by implicit or explicit standards of competence and conduct (Bayles, 1988). These standards help to ensure that professionals perform as expected and that the profession itself maintains quality and integrity. Accordingly, institutions are concerned with both the review and the responsible conduct of research. Because allegations of misconduct tend to be unique rather than routine at most institutions around the globe, few have extensive experience in responding to allegations. The uniqueness of allegations of misconduct makes it difficult for an institution to develop expertise in conducting inquiries and investigations (Rhoades, 2000; Lock, 1995; **Husemeyer**, 1995). However, a research misconduct allegation has the potential for a high impact, both on the individuals involved and the institution (Rhoades, 2000).

Much of the recently published literature concerning research ethics, integrity, and compliance comes from Northern and Western nations. Nevertheless, internationally collaborative research has become more commonplace in locations that may have fewer financial resources to develop ethics and compliance programs. Yet constructing such programs is possible. In this paper we discuss some of the difficulties inherent to setting up these programs in the developing world and describe one program that may serve as a model.

Difficulties with setting up ethics structures in developing countries

Perlman (2005) maintains that, in the United States, reliance on regulations to enforce ethics requirements has resulted in a focus on compliance with requirements rather than the ethical principles that underpin them (National Commission, 1979). Despite this shortcoming, the U.S. approach helps to ensure that vulnerable subjects are protected and that their rights, safety and welfare take priority over the interests of science.

The situation in many developing countries is very different due to a lack of national legislation that would form the required umbrella for ethics policies. In Botswana, for example, there is no national legislation on ethics. In particular, although the country has for years depended upon South Africa for specialized medical services, there is no tissue act to regulate the movement of human tissues across national borders, nor to oversee their disposal once laboratory procedures are completed. The Ministry of Health is the only ministry with an active ethics body. Its institutional review board (IRB) ensures adherence to standard international ethics. The lack of a national legislative framework is not unique to Botswana, but common across the sub-Saharan region.

This situation – like ploughing on parched ground — makes it very difficult for an academic institution to formulate and effectively enforce an ethics policy. More importantly, this explains in part why so many university faculty members and students lack awareness of the responsible conduct of research. It is not always clear whether faculty members flout the rules for responsible ethical conduct deliberately or out of ignorance. Although the scale of academic misconduct by staff at the University of Botswana (UB) is not well documented, cases involving both students and staff have occurred (Moahi et al., 2005). Some of these cases have involved both intellectual and financial misconduct and are usually handled confidentially within the university. Some cases, however, some cases have also reached the public media, putting the university's integrity at stake (Odubeng, 2004).

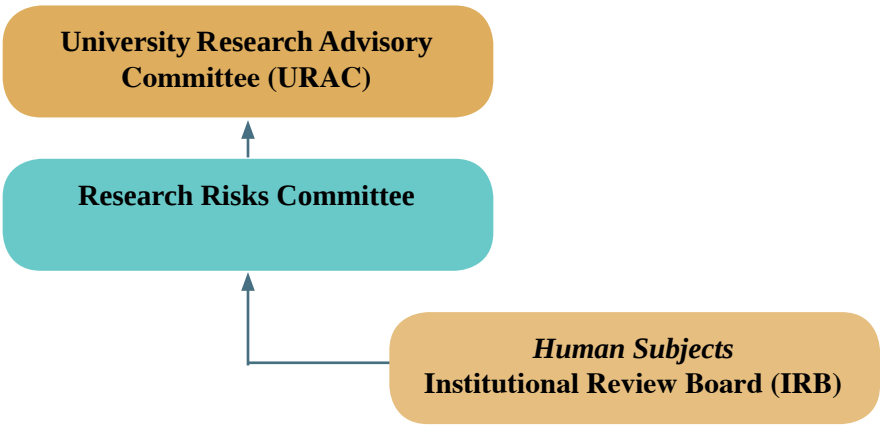
University of Botswana Ethics Policy

The objective of the ethics policy at the UB is to ensure that research is conducted according to internationally recognized ethical standards. Further, the implementation of the ethics policy represents another step toward handling of cases of academic misconduct and helping the university achieve its vision as a leading academic centre of excellence in Africa and the world.

The ethics policy at UB was approved in 2004. The Director of the Office of Research and Development (ORD) implements the policy through the Research Risks Committee (RRC). The RRC and its associated committees, including the IRB, the Animal Use and Care Committee (AUCC) and the Chemicals and other Hazardous Materials Committee (CHMC), were established in April 2005. The ORD Director is therefore responsible for ensuring that all research at UB follows both the ethical principles that have been set by the university and the laws and regulations governing research in Botswana. The Director also is responsible for fostering a culture of respect for research integrity; for ensuring the education of the ethics committees, researchers and staff on the ethical conduct of research; and for monitoring UB's ethics program.

Figure 1.

Reporting Structure for UB Human Subjects Institutional Review Board



The organization and administration of research ethics is demonstrated in Figure 1, which illustrates the relationship between the URAC, the RRC, and the IRB.

The University Research Advisory Committee (URAC), established in November 2002, advises the ORD on implementation of policy. The URAC consists of the Deans of each Faculty, the Director and Deputy Director of the ORD, the Dean of the School of Graduate Studies, the Faculty Research Committee Chairpersons, one person appointed by the Deputy Vice-Chancellor (Academic Affairs) to represent support staff, and the Manager of Special Projects from the Office of Financial Planning and Control.

The RRC has two primary roles:

1. To provide guidance in research ethics to the UB community, including, questions about misconduct (falsification, plagiarism, or misrepresentation of data), the level of contribution that warrants inclusion as an author on a publication, or ownership of a research idea. The RRC promotes awareness and compliance with the UB Policy on Ethics and Ethical Conduct of Research through periodic release of information to staff and students.

2. To review and make recommendations about all research proposed by UB staff or students. This responsibility is delegated to the three committees for which the RRC has oversight: the AUCC, the CHMC, and the IRB.

The UB Institutional Review Board for Protection of Human Subjects

The UB IRB is responsible for review of all human subject research activities consistent with U.S. federal regulations (Protection of Human Subjects, 2005). These broader definitions are critical to protecting the human subjects with whom UB investigators interact or about whom they obtain private information. When there is a question about whether an activity constitutes human subject research, the UB requires "a qualified person or persons other than the investigator or research team" to verify that the activity requires IRB review (Protection of Human Subjects).

IRB review is also extended to student research activities. In some courses, students collect data by using professional research methods, even though the work is not expected to contribute to generalizable knowledge. Because some methods involve human subjects, and in some instances place these subjects at risk, student research projects are reviewed and approved prior to initiation to assure that the rights and welfare of human subjects are protected.

To direct its operations, the UB IRB has established guidelines used by staff and students in both courses and research, and it has the authority to require adherence to these practices. Deviation from these standards is usually reported to the Director of ORD, who then takes further action as recommended by the RRC. The IRB also reviews all research protocols of staff and students in which human subjects are used. The committee is authorized to communicate approval and disapproval actions to those submitting the proposal, and is required to report all review outcomes to the RRC.

The IRB consists of 12 members appointed by the Director, ORD. Membership includes knowledgeable individuals from the local community, the Government, and UB. Additional individuals with special expertise may from time to time be designated as ad hoc members to assist the IRB. The committee is chaired by a member of the UB staff.

The IRB review process requires researchers to submit 12 copies each of the entire academic proposal, the completed UB application for Approval of Human Research, instructions to participants, the consent form, any questionnaires (translated as appropriate), and the curriculum vitae of the Principal Investigator(s).

The review process of the IRB consists of:

1. Discussion of any policy issues, conflict of interest or procedural matters.

2. Review of protocols.

    a. The IRB will establish and publicize to UB staff and students deadlines for submission of research projects for review.

    b. Each protocol is assigned to a member of the IRB for review. When additional expertise is required, the protocol may be assigned to an ad hoc member for review and presentation to the IRB.

    c. Review criteria are provided to the researcher and to the reviewer. A short, formal review with written comments is completed by the member to whom the review is assigned (see 2 b above) before the meeting, and will form the basis of the discussion during the meeting. Researchers may be asked to provide clarification or additional information to assist the deliberations of the IRB.

    d. The IRB acts on each research project it receives, and advises the researcher of the outcome. No research may be started until a research permit has been issued by the Ministry of Health.

    e. Some researchers have the habit of commencing research work before IRB approval is given. In view of that, the IRB will not accept requests for approval of research that is ongoing or completed and has not had prior approval.

The IRB is scheduled to meet at least quarterly, but may meet monthly if the protocols received for review call for that.

The IRB chair reports all board actions to the RRC, and communicates with the Chair of the RRC when conflicts of interest arise that affect the rights and welfare of participants. Conflicts may exist among IRB members and consultants, investigators, students, sponsors or administrators. Any case of research misconduct or serious or continuing noncompliance with regulations pertaining to research and/or university policy may be reported to the RRC as an allegation of misconduct by the IRB chair, any member of the IRB, human subjects or any other individual.

UB IRB pilot review of proposals.
The UB IRB began reviewing university research in November 2005 on a pilot basis for those researchers who received funding from URAC. The outcome of this first round of reviews is shown in Table 1. None of the proposals was deemed exempt from review; 20% qualified for expedited review and 80% were assigned to the full board. None of the proposals was approved on the first review, as all had both methodological and ethical issues that needed to be addressed. Sixty percent were approved on the second review; the IRB requested that two researchers attend a meeting to discuss and clarify their proposals. Four proposals are still pending.

Table 1

Statistics on Review of Research Proposals

Status of proposals	Number
Proposals received for review	10
Proposals exempted from review	0
Proposals for expedited review	2
Proposals for full board review	8
Proposals approved at 1st review	0
Proposals approved at 2nd review	6
Researchers invited to IRB meeting	2
Proposals pending	4

Among the challenges in operating the board are the following:

1. Time constraints – committee members often have limited time to dedicate to the IRB because of conflicting activities involved in teaching, research and other committee memberships. As a result, members who attend often do not form a quorum, which makes decision making difficult.

2. Administrative constraints – No staff member is dedicated solely to administration of the IRB. This responsibility was added to a staff member's already full work load. However, it soon became obvious that IRB administration itself is a full-time job, in terms of coordinating meetings, the protocol reviews, organizing paperwork, and communicating with researchers (even for this pilot project, which did not include all the research conducted by the University).

3. Ethical versus methodological review – while it is widely known that the IRB may review both the research and ethical considerations of a protocol, most of the methodological issues should be addressed by the committee allocating research funding. However, many questions regarding methodology were left to the IRB to clarify.

4. Monitoring of researcher compliance – continuous checking of projects to ensure that researchers are adhering to the regulations is impossible at this time, given the staffing situation. This problem is expected to become even more difficult once this pilot phase is over and review of all university research begins.

To alleviate some of these problems and improve operations, the UB IRB has made specific suggestions to the ORD. First, it has requested a dedicated staff member, trained in research ethics, to serve as the IRB Administrator. This will provide for smoother operation of the IRB and faster communication to researchers. The IRB also recommended that the committee allocating research funding conduct more thorough reviews to ensure that proposals approved for funding have sound methodologies that do not require further exhaustive review by the IRB. This has been addressed by revising the tools that the peer review panel uses to allocate funding. A more thorough methodological review may also alleviate the time commitment of IRB members, who could concentrate on ethical, rather than methodological, issues.

Responsible Conduct of Research Seminar Series

Researchers in many institutions globally must receive instruction in nine core areas of responsible conduct of research (RCR) to be eligible to receive public funding for research (ORI, 2005). These core areas and other relevant topics have been adopted by UB into a seminar series available throughout the academic year and targeted at increasing the awareness of researchers on issues related to RCR. The series focuses on aspects of planning, conducting and reviewing and reporting on research, as follows: Planning research: (a) research involving human subjects, (b) research involving animals, (c) research involving the use of chemicals, (d) management of research funds, and (e) conflict of interest and commitment; Conducting research: (a) data acquisition, management, sharing, and ownership, (b) mentor/trainee responsibilities; Reviewing and reporting research: (a) research collaboration, (b) publication practices and responsible authorship, and (c) peer review.

An RCR training needs survey was administered to 300 academic staff members simultaneously with the seminar series to assess the educational needs at UB in RCR and the handling of allegations of scientific misconduct. Responses from 115 individuals were received, which represented a 38% response rate. It was designed to identify who should receive training, what instructional materials were needed, the topics the training should address, useful teaching resources, formats and methods, and strategies for increasing awareness about RCR.

A majority of the respondents considered RCR training as useful primarily for graduate and undergraduate students, researchers, research assistants, training and development officers, Ethics Committee members, and financial project officers. A total of 82.1% of respondents considered seminars an appropriate format for delivering instructions in RCR; 59.5% cited a manual on RCR; 52.4% preferred Web-Based Modules and only 11.9% preferred audio tapes.

The topics recommended for RCR training programs are shown in Table 2. The main topics of interest for researchers were collaborative research and misconduct in research (78.6% in each case), authorship/publication (75%) and intellectual property (71.4%). For graduate students, the topics recommended were education in research misconduct (76.2%), research design (69%), intellectual property (63.1%) and scientific record keeping (61.9). For undergraduate students, misconduct in research (60.7%) was identified as a crucial topic, as well as research design (52.4%). The majority of researchers felt that more adequate instructional materials were needed for selected RCR topics. The primary topics included research design (71.1%), penalties for misconduct in research (57.9%), lab safety (53.5%), and misconduct in research (51.8%).

Table 2

RCR Topics that Training should Address and that Require Additional Instructional Materials

RCR Topics	Responses for research group (%)			Researcher responses for instructional materials (%)
	Researchers	*Grad students*	*Undergrad students*	
Research Design	69.0	69.0	52.4	71.1
Scientific record keeping	54.8	61.9	46.4	39.5
Human/Animal subjects	48.8	46.4	39.3	46.5
Lab safety	28.6	38.1	28.6	53.5
Funds management	61.9	41.7	27.4	35.1
Mentoring	63.1	28.6	20.2	34.2
Collaborative research	78.6	44.0	26.2	32.5
Authorship/Publication	75.0	59.5	32.1	37.7
Authorship of student work	56.0	53.0	46.4	22.8
Peer review	63.1	44.0	28.6	43.0
Intellectual property	71.4	63.1	45.2	48.2
Conflicts of interest and conflicts of commitment	59.5	36.9	21.4	36.0
Misconduct in research	78.6	76.2	60.7	51.8
Penalties for misconduct in research	60.7	60.7	46.4	57.9
Institutional policies on research misconduct	53.6	48.8	34.5	25.4
Whistle blower and / or reporting misconduct	53.6	48.8	34.5	3.5

Administrators at UB were also asked about the management of issues related to research misconduct. The Deputy Vice Chancellor of Academic Affairs, all Deans and Heads of Departments were identified as the administrators most needing training in this area (Table 3). However, it must be noted that some respondents suggested that all researchers needed training in the management of allegations of misconduct.

The specific topics in terms of the management of allegations are shown in Table 4. Among the topics for administrators, policy requirements (62.5%), reporting to the UB community and the public media (62.5%), restoring reputation (58.3%), and treatment of respondents and whistle blowers (54.2%) were the primary ones identified. For research integrity officials, important topics included developing investigation plans (54.2%), handling evidence and sequestering of data (54.2%), interviewing (50%), and responding to retaliation complaints (50.0%). For researchers, the important topics were conflicts of interest (50%), maintaining confidentiality (48.5%) and developing investigation plans (45.8%). In terms of the format of the training program,

Table 3

Type of Staff to Receive Training on Managing Allegations

Staff	*Positive response (%)*
University Administrators	
Vice Chancellor (VC)	58.3
Deputy VC Academic Affairs	70.8
Deputy VC Financial Affairs	45.8
Deputy VC Students' Affairs	45.8
Deans	87.5
Heads of Departments	83.3
Directors of Centers	66.7
Public Affairs staff	44.1
Research Integrity Officials	
Chair, research risks committee	54.2
Members, Research Risks Committees	45.8
Members, Research Ethics Committees	66.7
Researchers	
Academic staff	79.2
Others	
Faculty Research and Publication Committee	58.3
Others	25.0

the majority (69.6%) felt that the most effective format was within a leadership training program or an Administrators Annual Retreat organized jointly by ORD and the Centre for Academic Development (CAD). Over half (52.6%) also felt that RCR training should be included in the induction program for Heads of Departments.

The majority of administrators felt it was important that feedback on allegations of misconduct at UB be provided to university staff, but less so to the press and the general public. The data showed that 90.9% wanted feedback on publicly reported cases while 69.6% wanted such cases to be publicized by the press. Administrators also suggested that guidelines, examples of best practices and case studies, as well as a dedicated research integrity officer, were the most appropriate resources for the management of allegations of misconduct.

Ploughing On Parched Ground?

This paper highlights the limitations within which developing country institutions such as the University of Botswana work. While the ethical principles outlined in the Belmont Report seem to have broad reach, an emphasis on compliance rather than ethics may lead to untenable approaches in the developing world. Throughout Southern Africa, problems with ascertaining compliance may in part be due to the lack of a national framework to support relevant policies relating to ethics and associated legislation such as intellectual property and data management. Notwithstanding the shortage of overarching ethics legislation, however, the University of Botswana has

Table 4

Topics Training should Address

Topics	*Positive response (%)*			
	UB Admin	*RI Officials*	*Researchers*	*Others*
Policy requirements	62.5	37.5	37.5	8.3
Maintaining confidentiality	45.8	41.7	48.5	8.3
Protection against conflicts of interests	33.3	37.5	50.0	4.2
Assuring appropriate expertise	29.2	29.2	25.0	4.2
Treatment of respondents & whistle blowers	54.2	45.8	25.0	4.2
Developing investigation plans	29.2	54.2	45.8	4.2
Handling evidence and sequestering of data	25.0	54.2	33.3	8.3
Requirement of proof	37.5	45.8	20.8	4.2
Interviewing	20.8	50.0	41.7	8.3
Preparing reports	16.7	41.7	25.0	8.3
Responding to retaliation complaints	41.7	50.0	25.0	8.3
Restoring reputation	58.3	37.5	16.7	8.3
Reporting to UB community	62.5	29.2	25.0	8.3
Reporting to public media	62.5	20.8	12.5	8.3
Departmental/Faculty Appeals	25.0	29.2	29.2	12.5
Research Risks Appeals	29.2	41.7	25.0	4.2
Committee hearings	20.8	45.8	16.7	8.3
Others	4.2	4.2	4.2	4.2

been able to achieve a culture of responsible ethical conduct among its researchers. While a lack of support from above and complimentarity with others addressing the same problems may be likened to ploughing on parched ground, the success of the University of Botswana can be replicated by institutions in similar settings.

References

Bayles, M. (1988). *Professional ethics* (2nd ed.). Belmont, CA: Wadsworth.

Crigger, B. (1992). Twenty years after: the legacy of the Tuskegee syphilis study. *Hastings Center Report,* 22(6), 29.

Deyhle, D.L., Hess, G.A., Jr., & LeCompte, M.D. (1992). Approaching ethical issues for qualitative researches in education. In M.D. LeCompte, W.L. Millroy, & J. Preissle (Eds.), *The handbook of qualitative research in education* (pp. 597-643). Toronto: Academic Press Inc.

Doberneck, D. (Ed.). (2004, Spring). Research Mentoring. *Michigan State University Research Integrity Newsletter,* 7(4). Retrieved February 14, 2006 from www.msu.edu/user/gradschl/all/ris04.pdf

Husemeyer, R.P. (1995). Handling scientific fraud. *British Medical Journal, 311,* 261-262.

Lock, S. (1995). Lessons from the Pearce affair: Handling scientific fraud. *British Medical Journal, 310,* 1547-8.

Moahi, K., Becker, C, Lee, M., Kuruba, G., Jackson-Malete, J., Masupo, S., et al. (2005). *Report of the task group on academic dishonesty in the University of Botswana.* University of Botswana.

National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research (1979). *The Belmont Report: Ethical principles and guidelines for the protection of human subjects.* Washington, DC: Department of Health, Education and Welfare.

Odubeng, M. (2004, February). UB exam papers disappear. *Mmegi Online Newspaper,* 21(24). Retrieved February 16, 2006 from http://www.mmegi.bw/2004/February/Monday16/10584761891225.html

Office of Research Integrity. (2005, October). *Teaching tools for responsible conduct of research.* Presented at the annual meeting of the Society of Research Administrators International, Milwaukee, WI.

Perlman, D. (2005). Putting the ethics back into research ethics: A process for ethical reflection for human research protection. *The Journal of Research Administration*, 37(1), 13-22.

Protection of Human Research Subjects, 45 C.F.R. § 46 (2005).

Rhoades, L.J. (2000).The American experience: Lessons learned. *Science and Engineering Ethics,* 6(1), 95-107.

The National Academies Press. (2002). Integrity in scientific research: *Creating an environment that promotes responsible conduct.* Retrieved February 16, 2006 from http://www.nap.edu/catalog/10430.html